UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 4, 2022

ALIGOS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39617**	**82-4724808**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

One Corporate Dr., 2nd Floor
South San Francisco, California 94080
(Address of Principal Executive Offices) (Zip Code)

(800) 466-6059
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	ALGS	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On August 4, 2022, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 2.02 and the attached Exhibit 99.1 are being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall they be deemed to be incorporated by reference in any filing made by the Registrant under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

Exhibit 99.1. Press release dated August 4, 2022

Exhibit 104. Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Aligos Therapeutics, Inc.

Date: August 4, 2022

By: /s/ Lesley Ann Calhoun
Lesley Ann Calhoun
Executive Vice President, Chief Financial Officer

EXHIBIT 99.1

Aligos Therapeutics Reports Recent Business Progress and Second Quarter 2022 Financial Results

SOUTH SAN FRANCISCO, Calif., Aug. 04, 2022 (GLOBE NEWSWIRE) -- Aligos Therapeutics, Inc. (Nasdaq: ALGS), a clinical stage biopharmaceutical company focused on developing novel therapeutics to address unmet medical needs in viral and liver diseases, today reported recent business progress and financial results for the second quarter June 30, 2022.

“In the second quarter, we continued to make strong progress in advancing our drug candidates and discovery programs,” said Lawrence Blatt, PhD, MBA, CEO and Chairman of the Board at Aligos. “We completed enrollment in multiple cohorts across our Phase 1 CAM-2 and NASH studies and presented posters for these and other drug candidates and discovery programs at the recent International Liver Congress meeting hosted by the European Association for the Study of the Liver (EASL). We are similarly off to a strong start in Q3, where we have initiated enrollment in a 12-week cohort evaluating the safety and chronic suppressive activity of ALG-000184 in chronic hepatitis B (CHB) patients. We also remain on track to submit a clinical trial application (CTA) this quarter to evaluate our siRNA drug candidate, ALG-125755, in healthy volunteers and CHB patients. We believe our siRNA, which is designed to lower HBsAg levels, is an important addition to our clinical portfolio and has the potential to be a cornerstone of our functional cure strategy.”

Recent Business Progress

Aligos Portfolio of Drug Candidates

HBV Programs

- ALG-000184 (CAM-2): Enrollment of HBeAg positive subjects in 28-day and 12-week cohorts evaluating various dose levels is ongoing. We plan to share data from HBeAg positive cohorts at a scientific conference in Q4 2022.
- ALG-125755 (siRNA): Phase 1 enabling nonclinical studies are nearly complete. We are on track to file a CTA in Q3 2022 to enable the evaluation of the safety, tolerability, pharmacokinetics, and antiviral activity of ALG-125755. Dosing is planned to begin in healthy volunteers in Q4 2022 and in CHB subjects in Q1 2023.

NASH

- ALG-055009: Enrollment of hyperlipidemic subjects in all 4 cohorts of the multiple ascending dose portion of our Phase 1 study is now complete. We are currently analyzing these data and remain on track to share top line data from the single and multiple ascending dose portions of this study in Q3 2022.

COVID-19 3CL Protease Inhibitor (PI) Program

- ALG-097558: Evaluation of ALG-097558 in the hamster SARS-CoV-2 infection model indicates that when dosed prior to infection or up to 24 hours post-infection, the compound causes a significant reduction in the levels of infectious virus in the lungs.
- Phase 1 enabling nonclinical studies are on track to be initiated in H2 2022. A subsequent CTA filing for a Phase 1 study evaluating the safety and pharmacokinetics of ALG-097558 in healthy volunteers is planned for Q1 2023.

COVID-19 3CL Protease Inhibitor Resistance Profiling

The potential for the emergence of viral resistance to 3CL protease inhibitors used to treat COVID-19 is of considerable concern. Together with our collaborators at KU Leuven, including its Centre for Drug Design and Discovery (CD3), a drug discovery unit and investment fund of KU Leuven, and the Rega Institute for Medical Research, we have begun to investigate the viral resistance profile of our 3CL protease inhibitors. A resistant mutant was derived by incubating SARS-CoV-2 infected cells with an early lead compound, ALG-097161. We identified a combination of 3 amino acid substitutions in the 3CL protease (L50F E166A L167F) that are associated with a greater than 50-fold increase in the EC_{50} values for ALG-097161 and PF-07321332 (nirmatrelvir) when assessed in a biochemical assay. In contrast, when ALG-097558 was profiled against the L50F E166A L167F resistant mutant, only a 3-fold shift in the EC_{50} value was observed. Experiments to further evaluate the viral resistance profile of ALG-097558 are currently ongoing.

Financial Results for the Second Quarter 2022

Cash, cash equivalents and investments totaled $159.3 million as of June 30, 2022, compared with $205.8 million as of December 31, 2021. We continue to believe our cash balance provides sufficient cash to fund planned operations into the first half of 2024.

Net losses for the three months ended June 30, 2022, were $19.9 million or basic and diluted net loss per common share of ($0.47), compared to net losses of $29.8 million or basic and diluted net loss per common share of $(0.79) for the three months ended June 30, 2021.

Research and development (R&D) expenses for the three months ended June 30, 2022, were $16.5 million compared with $24.6 million for the same period of 2021. The decrease in R&D expenses for this comparative period is primarily attributable to our continued wind-down related to the discontinuation of our STOPS and ASO programs offset by our expenditures related to the ongoing development and manufacturing activities associated with our CAM and NASH clinical program activities. Total R&D stock-based compensation expense incurred for the three months ended June 30, 2022, was $2.2 million compared with $2.0 million for the same period of 2021.

General and administrative (G&A) expenses for the three months ended June 30, 2022, were $7.6 million compared with $6.6 million for the same period of 2021. The increase in G&A expenses for this comparative period is primarily attributable to routine employee and facility related costs. Total G&A stock-based compensation expense incurred for the three months ended June 30, 2022, was $1.8 million compared with $1.5 million for the same period of 2021.

About Aligos

Aligos Therapeutics, Inc. is a clinical stage biopharmaceutical company that was founded in 2018 with the mission to become a world leader in the treatment of viral infections and liver diseases. Aligos is focused on the discovery and development of targeted antiviral therapies for chronic hepatitis B (CHB) and coronaviruses as well as leveraging its expertise in liver diseases to create targeted therapeutics for nonalcoholic steatohepatitis (NASH). Aligos' strategy is to harness the deep expertise and decades of drug development experience its team has in liver disease, particularly viral hepatitis, to rapidly advance its pipeline of potentially best-in-class molecules.

Forward-Looking Statement

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this press release that are not historical facts may be considered "forward-looking statements," including without limitation statements regarding, our confidence that combinations of drug candidates from our CHB portfolio have the potential to increase the rate of functional cure in CHB subjects; with respect to our siRNA drug candidate, ALG-125755, our remaining on track to submit a clinical trial application (CTA) in Q3 2022 to evaluate such candidate in healthy volunteers and CHB patients with the plan to begin dosing in healthy volunteers in Q4 2022 and in CHB subjects in Q1 2023 and our belief that our siRNA is an important addition to our clinical portfolio and has the potential to be a cornerstone of our functional cure strategy; with respect to ALG-000184 (prodrug of ALG-001075), our ongoing enrollment of HBeAg positive subjects in 28-day and 12-week cohorts and our plan to share at a scientific conference in Q4 2022 data from such HBeAg positive cohorts; with respect to ALG-055009 for NASH, our remaining on track to share top line data from the single and multiple ascending dose portions of our Phase 1 study in Q3 2022; with respect to our COVID-19 protease inhibitor program, our being on track to initiate our Phase 1 enabling nonclinical studies in H2 2022 for ALG-097558, our plan for a subsequent CTA filing for a Phase 1 study evaluating the safety and pharmacokinetics of ALG-097558 in healthy volunteers in Q1 2023, the potential for the emergence of viral resistance to 3CL protease inhibitors used to treat COVID-19 and our beginning to investigate the viral resistance profile of our 3CL protease inhibitors; and our continued belief that our cash balance provides sufficient cash to fund planned operations into the first half of 2024. Forward-looking statements are typically, but not always, identified by the use of words such as "may," "will," "would," "believe," "intend," "plan," "anticipate," "estimate," "expect," and other similar terminology indicating future results. Such forward looking statements are subject to substantial risks and uncertainties that could cause our development programs, future results, performance, or achievements to differ materially from those anticipated in the forward-looking statements. Such risks and uncertainties include without limitation risks and uncertainties inherent in the drug development process, including Aligos's clinical-stage of development, the process of designing and conducting clinical trials, the regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing drug products, Aligos's ability to successfully establish, protect and defend its intellectual property, other matters that could affect the sufficiency of Aligos's capital resources to fund operations, reliance on third parties for manufacturing and development efforts, changes in the competitive landscape and the effects on our business of the worldwide COVID-19 pandemic and the developing conflict between Russia and Ukraine. For a further description of the risks and uncertainties that could cause actual results to differ from those anticipated in these forward-looking statements, as well as risks relating to the business of Aligos in general, see Aligos's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 4, 2022 and its future periodic reports to be filed or submitted with the Securities and Exchange Commission. Except as required by law, Aligos undertakes no obligation to update any forward-looking statements to reflect new information, events or circumstances, or to reflect the occurrence of unanticipated events.

Aligos Therapeutics, Inc
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenue from Collaborations	$ 3,693	$ 1,545	$ 6,264	$ 2,455

Operating Expenses:				
Research and development	16,510	24,554	48,186	47,422
General and administrative	7,576	6,556	14,028	12,337
Total operating expenses	24,086	31,110	62,214	59,759
Loss from operations	(20,393)	(29,565)	(55,950)	(57,304)
Interest and other income (expense), net	516	(225)	510	(114)
Loss before income tax expense	(19,877)	(29,790)	(55,440)	(57,418)
Income tax expense	(47)	(28)	(99)	(74)
Net loss	$ (19,924)	$ (29,818)	$ (55,539)	$ (57,492)
Basic and diluted net loss per common share	$ (0.47)	$ (0.79)	$ (1.30)	$ (1.53)
Weighted-average number of shares used in computing basic and diluted net loss per common share	42,665,598	37,619,039	42,590,479	37,526,650

Aligos Therapeutics, Inc
Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2022	December 31, 2021
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents	$ 71,172	$ 186,816
Short-term investments	88,172	3,918
Prepaid expenses and other current assets	8,341	13,690
Total current assets	167,685	204,424
Long-term investments	-	15,110
Other assets	14,838	15,835
Total assets	$ 182,523	$ 235,369
Liabilities and Stockholders' Equity		
Current liabilities	31,653	$ 38,957
Other liabilities, noncurrent	13,889	11,681
Total liabilities	45,542	50,638
Total stockholders' equity	136,981	184,731
Total liabilities and stockholders' equity	$ 182,523	$ 235,369

(1) The condensed, consolidated balance sheet at December 31, 2021 has been derived from the audited consolidated financial statements at that date included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

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